IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA,

Plaintiff,

vs. Crim. No. 13-0571 MCA

IRA STOCKTON, *et al.*,

Defendants.

ORDER

On July 8, 2015, the Court in furtherance of its role as gatekeeper conducted a *Daubert* [1] hearing to determine the admissibility of expert testimony relating to the issue of whether the "hallucinogenic effect on the central nervous system," 21 U.S.C. § 802(32)(A)(ii), of each of five alleged controlled substance analogues commonly known as AM-2201, AM-694, JWH-250, UR-144 and XLR-11 is "substantially similar or greater than," *id.*, the hallucinogenic effect of JWH-018, a scheduled controlled substance. The Court has considered the written submissions of the parties, the evidence tendered to the Court at the July 8, 2015 evidentiary hearing, the record in this case and the applicable law, and is otherwise fully advised. This order references the Joint Motion referenced at [Doc. 374]

[1] *Daubert v. Merrell Dow. Pharm., Inc.*, 509 U.S. 579 (1993).

Dr. Trecki is Qualified to Testify as an Expert in Pharmacology

The witness who is the subject of this Order is Jordan Trecki, Ph.D.,[2] a pharmacologist employed by the Drug Enforcement Administration.[3] Dr. Trecki's duties include research related to the scheduling of substances and, as in the present case, providing expert testimony on behalf of the government. [Doc. 407 at 14] There is no dispute, and the Court has found, that this well-credentialed scientist is qualified by "knowledge, skill, experience, training and education, Fed. Evid. Rule 702, to testify about pharmacological principles and methods as they relate to synthetic cannabinoids. [Doc. 407 at 14][4]

Having determined that Dr. Trecki is qualified within the meaning of Rule 702, the Court next considers whether Dr. Trecki's opinion testimony satisfies the four prongs of Rule 702, giving due regard to the factors identified by the Supreme Court in *Daubert*, 509 U.S. at 593-94.

[2] The United States initially designated DEA pharmacologist Li Fang, Ph.D., to speak to CNS effect of the alleged CSAs. Dr. Trecki subsequently was substituted for Dr. Fang. [Doc. 390]

[3] The Court is aware that testimony by DEA scientists such as Dr. Trecki has been admitted in CSAEA prosecutions. That other courts have admitted such evidence does not excuse this Court from exercising its gatekeeping function *de novo*. *Cf.* National Academy of Sciences, *Strengthening Forensic Science in the United States: A Path Forward* 106-08 (2009) (criticizing federal courts for routinely failing to screen forensic evidence for scientific reliability; observing that federal courts often admit forensic evidence citing earlier decisions, rather than relying the facts established at a *Daubert* hearing).

[4] The United States, as the proponent of Dr. Trecki's testimony, has the burden of establishing by a preponderance of the evidence the requirements of Rule 702. Fed. Evid. Rule 702, Advisory Committee's Note to 2000 Amendments. Courts must take care to avoid the legal error of reversing the burden of production. 1 *Faigman, et al., Modern Scientific Evidence: The Law and Science of Expert Testimony* § 1:9 at 30 (2014-15 ed.).

Dr. Trecki's Opinions Will Not be Helpful to the Jury

Dr. Trecki has opined in cookie-cutter fashion that each of the alleged CSAs "has a hallucinogenic effect on the central nervous system that is *substantially similar* to the hallucinogenic effect on the central nervous system of JWH-018." [Gov't Ex. 6 (emphasis added)] There is no dispute that "substantially similar" is not a scientific concept. Dr. Trecki testified that scientists employ the term only when testifying as experts in criminal prosecutions under the Controlled Substances Act and the Controlled Substance Analogue Enforcement Act. [Doc. 407 at 36] He estimated that probably there are less than 30 scientists who have given an opinion using the term "substantially similar." [Doc. 407 at 37]

Due to the absence of any generally-accepted scientific definition of "substantially similar," Dr. Trecki resorted to a dictionary, conflating common dictionary definitions of "substantially" and "similar." He testified that he understood "substantially" to mean "consisting of or relating to substance; that which is *largely but not wholly* specified," and "similar" to mean "having characteristics in common." [Doc. 407 at 34 (emphasis added)]. Dr. Trecki testified that he understands "substantially similar" to mean "relating to a substance with common characteristics." [Doc. 407 at 34] The Court does not take issue with Dr. Trecki's resort to a dictionary. *See McFadden v. United States*, 135 S. Ct. 2298, 2304 (2015) (resorting to dictionary to clarify meaning of "*a* controlled substance"). The problem is that his definition omits the crucial concept of "largely but not wholly." Instead of "having characteristics largely, but not wholly, in common," Dr. Trecki has used a definition that improperly reduces the Government's substantive burden. The Court

finds that Dr. Trecki based his opinions on an erroneous definition of "substantially similar."[5]

Dr. Trecki's opinions are flawed in another crucial respect: his misunderstanding of the relationship of potency to "substantially similar or greater than." Section 802(32)(A)(ii) identifies three types of effects on the central nervous system: stimulant, depressant, or hallucinogenic.[6] To fall within § 802(32)(A)(ii), a drug must produce one or more of the three types of CNS effects identified by Congress. But § 802(32)(A)(ii) also requires that the type of effect produced by the alleged CSA be substantially similar *or greater than* the effect of the scheduled substance to which it is being compared. The juxtaposition of "substantially similar" and "or greater than" suggests to the Court that Congress intended the second prong of the definition of a CSA to address both the *type* (stimulant, depressant, or hallucinogenic) *and* the *intensity* of a CSA's effect. Indeed, the Court does not understand how Dr. Trecki meaningfully can compare the effects of two drugs without taking into account their relative potency. As the Court reads § 802(32)(A)(ii), a drug that has the same general type of CNS effect as the pertinent scheduled drug, but that is significantly less potent, would not satisfy the substantially similar requirement. *See United States v. Orchard*, 332 F.3d 1133, 1138 (8th Cir. 2003)

[5]Our Court of Appeals has recently observed that "[i]t's an open question, after all, what it exactly means for chemicals to have a 'substantially similar' chemical structure—or effect." *United States v. Makkar*, 810 F.3d 1139, 1143 (10th Cir. 2015).

[6] The Government has elected to focus on the "hallucinogenic" alternative. "Hallucinogenic" is not defined by the CSAEA. Webster's dictionary defines "hallucinogen" as "a substance that induces hallucinations." *Webster's Third Int'l Dictionary* 1023 (1976). It defines "hallucination" as "perception of objects with no reality; experience of sensations with no external cause." *Id.* The only psychotropic effect of cannabinoids Dr. Trecki described was euphoria.

(discussing whether "similar quantities" of MSG and 1,4-Butanediol have "similar effects" and whether the effect of the two substances are "similar in intensity" in the course of rejecting argument that § 802(32)(A)(ii) is unconstitutionally vague). Requiring that an alleged CSA have both a type and an intensity of effect as the scheduled drug provides some assurance that the alleged CSA presents the same public health risks as the scheduled drug.

On cross-examination Dr. Trecki correctly acknowledged that "substantially similar or greater than" can also relate to the potency of the alleged CSAs as compared to JWH-018. [Doc. 407 at 70] Yet, shortly afterward, he contradicted himself, testifying that "prong two of the Analogue act does not reflect potency." [Doc. 407 at 74]

Rule 702 requires as a condition of admissibility that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Opinion testimony incorporating legally incorrect standards will not help the jury. Rather, it will tend to confuse the issues and mislead the jury. The Court finds that the probative value of Dr. Trecki's opinion testimony is substantially outweighed by its tendency to confuse the issues and mislead the jury. The Court will exclude the opinions tendered in Government Exhibit 6 pursuant to Fed. Evid. Rules 403 and 702(a).

Dr. Trecki Lacks Sufficient Facts or Data to Offer an Opinion on the Hallucinogenic Effects of AM-694 on the Human CNS

Dr. Trecki works in an office, not a laboratory. [Doc. 407 at 44] His methodology comprises a survey of structure-activity relationship studies,[7] *in vitro* binding[8] and functional assay studies,[9] and *in vivo* tetrad and drug discrimination studies using rodents as subjects, supplemented by anecdotal human case studies.[10] [Doc. 407 at 45; Gov't Ex. 6.] Dr. Trecki testified that he "used every possible piece of information involving the substances in this case that were available." [Doc. 407 at 42] Dr. Trecki relied on SAR studies and *in vitro* binding and functional assays for each of the five alleged CSAs. Dr. Trecki relied on both *in vivo* tetrad and drug discrimination results for UR-144 and XLR-11; and *in vivo* drug discrimination results for AM-2201and JWH-250.

Dr. Trecki had no *in vivo* results at all for AM-694. This is of concern to the Court because according to Dr. Trecki only *in vivo* results correlate highly with human user effects. *In vitro* binding assays provide limited information and *in vitro* functional assays do not necessarily translate to humans. [Gov't Ex. 5] Notwithstanding the absence of *in*

[7] Dr. Trecki provided two examples of how SARs can be used to rule out drugs. [Doc. 407 at 20] He testified more generally that SARs can predict pharmacological effects "with some certainty." [Doc. 407 at 21] Upon examination by the Court, Dr. Trecki testified that based on SARs he believed that it was "likely" that XLR-11 was substantially similar to JWH-018. [Doc. 407 at 87] He could not or would not state a level of confidence to which "likely corresponds, nor could he place "likely" on a spectrum of likelihood ranging from "may be likely" to "highly likely". [*Id.*]

[8] Dr. Trecki testified that *in vitro* binding assays cannot tell "what it's going to do, what the pharmacological effects downstream are." [Doc. 407 at 22]

[9] Dr. Trecki testified that *in vitro* functional assays determine whether a substance that binds to a receptor functions as an agonist or antagonist. [Doc. 407 at 23] He further testified that "[t]he functional assay results can be used to determine potency, *but not as it translates into humans*." [*Id.* (emphasis added)]

[10]Dr. Trecki testified that user reports are not given much weight since the toxicology usually cannot be confirmed. The Court is concerned that anecdotal human case studies rely on a biased sample consisting of outliers. J. Wiley, *et al., Hijacking of Basic Research: The Case of Synthetic Cannabinoids*, 6 (RTI Press publication No. OP-0007-1111) (Nov. 2011) *available at* http://www.rti.org/publications/rtipress.cfm?pubid=17971

vivo studies for AM-694, Dr. Trecki opined with the same level of confidence as for UR-144 and XLR-11—for which both tetrad and drug discrimination results were available—that AM-694 "has a hallucinogenic effect on the central nervous system that is substantially similar to the hallucinogenic effect on the central nervous system of JWH-018." The Court finds that due to the absence of *in vivo* test results for AM-694, the limited information provided by the *in vitro* binding assay, and the non-transferability of the *in vitro* functional assay, Dr. Trecki lacked sufficient facts or data to reliably opine AM-694 has substantially similar or greater CSN effects in humans as JWH-018. *Cf. United States v. Fedida*, 942 F. Supp. 2d 1270, 1280-82 (M.D. Fla. 2013). With respect to AM-694, "there is simply too great an analytical gap between the data and the opinion offered." *General Elec. v. Joiner*, 522 U.S. 136, 146 (1997). Moreover, Dr. Trecki's willingness to unqualifiedly opine that the hallucinogenic effect AM-694 is substantially similar to that of JWH-018 notwithstanding the absence of *in vivo* studies, the limited information provided by the *in vitro* binding assay, and the non-transferability of the *in vitro* functional assay causes the Court to question whether Dr. Trecki applies his methodology in an outcome-determinative, rather than a scientifically principled, manner.

Dr. Trecki Has Not Reliably Applied the Underlying Methods and Principles

The Court finds that SARs, *in vitro* binding and functional assays, and *in vivo* tetrad and drug discrimination assays are recognized methods for investigating the pharmacological properties of synthetic cannabinoids. Used in their proper context, these

assays constitute reliable principles and methods.[11] However, they have not been scientifically validated, singly or in combination, as a reliable method for unqualifiedly determining the hallucinogenic effects of synthetic cannabinoids on the human CNS. At present, these methods support working hypotheses about the hallucinogenic effects of synthetic cannabinoids on the human CNS—hypotheses which have yet to be validated due to practical, legal and ethical constraints on studies using human subjects. [Doc. 407 at 200-01 ("And at some point either you have to end or you end with an estimate, you still have a hypothesis; or you have to do the actual testing in humans, and then you have confirmed, or not, that hypothesis.")]; M. Castaneto, *et al.*, *Synthetic cannabinoids: Epidemiology, pharmacodynamics, and clinical implications*, Drug and Alcohol Depend. § 4.1 (August 2014) (surveying electronic literature; concluding that "[h]uman controlled SC administration studies and systematic *in vitro* and *in vivo* pharmacokinetic studies are needed to fill in important gaps in our knowledge of SC pharmacokinetics . . . . Human studies will be difficult to conduct in the US, as they must go through a rigorous multi-agency approval process . . . .").[12] The scientists who accept Dr. Trecki's methodology are a handful of colleagues at the DEA, who, like Dr. Trecki, are captive experts employed by the Government. The only peer review to which Dr. Trecki's methodology arguably may have been subjected is what the Court would characterize as "in house" peer

[11]The Court is not questioning Dr. Trecki's practice of consulting peer-reviewed scientific studies: "'data' is intended to encompass the reliable opinions of other experts." Fed. Evid. Rule 702, Advisory Committee's Note to 2000 Amendment. Rather, the Court's concern is whether Dr. Trecki has used the data produced by these studies in a scientifically responsible manner.

[12] The Court is not suggesting that the DEA is bound by FDA standards for approving new drugs. Dr. DeCaprio, a highly-credentialed and credible defense expert, testified that "there could be controlled human exposure studies which occur outside of the drug development paradigm." [Doc. 407 at 192]

review by his colleagues at the DEA. The Court finds that the unqualified opinions[13] set out by Dr. Trecki in his Rule 16 Summaries of Expert Opinion and Bases [Gov't Ex. 5] imply a level of confidence that exceeds the current state of scientific knowledge, and therefore do not represent the reliable application of otherwise reliable scientific methods to the facts of this case as required by Rule 702(d).[14]

Dr. Trecki May Testify to the Relevant Scientific Principles

An expert may testify in the form of "a dissertation or exposition of scientific . . . principles relevant to the case, leaving the trier of fact to apply them to the facts." Fed. Evid. Rule 702, Advisory Committee Note to 1972 Proposed Rules. If he is able, Dr. Trecki may use his knowledge of pharmacology to describe the forms (*e.g.*, auditory, visual, somatic, temporal) and intensities of the hallucinogenic effects produced by JWH-018, AM-2201, JWH-250, UR-144 and XLR-11, leaving it to the jury to compare these effects and reach a conclusion as to whether the hallucinogenic effects of the alleged CSAs in humans are substantially similar or greater than those of JWH-018.[15] To assist the jury in evaluating his testimony, Dr. Trecki should be prepared to testify as to "where

[13]By way of comparison, the authors of the *in vivo* study of XLR-11 and UR-144 commissioned by the DEA observed that "these results *suggest* that XLR-11 and UR-144 are psychoactive CB_1 receptor agonists." [Def. Ex. I at 18 (Emphasis added)]. They also qualified their results by limiting them to "this animal model." *Id.*

[14] As noted above, Dr. Trecki is involved in scheduling determinations. Evidence that justifies scheduling a substance based upon a *possible* harmful effect may not suffice to prove an *actual* effect in a court of law. *See Glastetter v. Novaris Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("The FDA will remove drugs from the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability.").

[15]DEA agent Evan Miyamoto, another proposed Government witness, testified during direct examination at a subsequent *Daubert* hearing that based on his review of a range of anecdotal reports [Tr. (October 14, 2015) at 441-42] he believes that the effects of synthetic cannabinoids are "very different from marijuana," "nothing, really, like marijuana," [Tr. (October 14, 2015) at 422] a conclusion diametrically at odds with the Government's overall position. This is the unusual case where there are dueling experts on the prosecution's side of the case.

on the continuum of relative certainty" his statements lie. 4 Faigman, *supra*, § 30:36. The Court finds that, so limited, Dr. Trecki's testimony satisfies the requirements set out in Rule 702(a)-(d).[16]

Conclusion

To summarize, the Court has found that Dr. Trecki's opinions as to whether the hallucinogenic effect of the CSAs on the human CNS is substantially similar or greater than the hallucinogenic effects of JWH-018 are based on erroneous legal standards and are not helpful to the jury. The Court has found that Dr. Trecki's unqualified opinions that each alleged CSA "has a hallucinogenic effect on the central nervous system that is substantially similar to the hallucinogenic effect on the central nervous system of JWH-018" imply a level of confidence that exceeds the current state of scientific knowledge, and therefore do not represent the reliable application of otherwise reliable scientific methods to the facts of this case as required by Rule 702(d). The Court further has found that Dr. Trecki lacks sufficient facts or data to reliably testify about the hallucinogenic effects of AM-694 on the human CNS. Lastly, the Court has found that testimony by Dr. Trecki in the form of a dissertation or exposition of the current state of scientific knowledge about the hallucinogenic effects of JWH-0018 and the alleged CSAs AM-2201, JWH-250, UR-144 and XLR-11will be helpful to the jury, will be based on

[16]At trial, the Government will have to prove the elements of § 802(32)(A)(ii) beyond a reasonable doubt—"the very high level of probability required by the Constitution in criminal cases." *Victor v. Neb.*, 511 U.S. 1, 14 (1994). The Government should not assume from the fact that the Court has ruled that Dr. Trecki's testimony is admissible that the Court has concluded that his testimony is *sufficient* to satisfy the Government's burden of proof. *See Reference Manual on Scientific Evidence* 20-21 (3d ed. 2011) (examining relationship of admissibility to sufficiency of evidence; contrasting *Daubert* and *Joiner*).

sufficient facts or data, and will result from the reliable application of reliable principles and methods to the facts of this case.

So ordered this 2nd day of May, 2016

M. CHRISTINA ARMIJO
Chief United States District Judge